BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :		(11) International Publication Number:	WO 97/00054
A61F 2/44, A61B 17/70	A1	(43) International Publication Date:	3 January 1997 (03.01.97)

(21) International Application Number: PCT/SE96/00797

(22) International Filing Date: 18 June 1996 (18.06.96)

(30) Priority Data:

9502224-0	19 June 1995 (19.06.95)	SE
9503191-0	14 September 1995 (14.09.95)	SE

(71)(72) Applicant and Inventor: OLERUD, Sven [SE/SE]; Villa Malmen, S-740 11 Länna (SE).

(74) Agent: BLOMBERG & CO., SKANDINAVISKA PATENTBYRÅN AB; P.O. Box 14031, S-104 40 Stockholm (SE).

(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

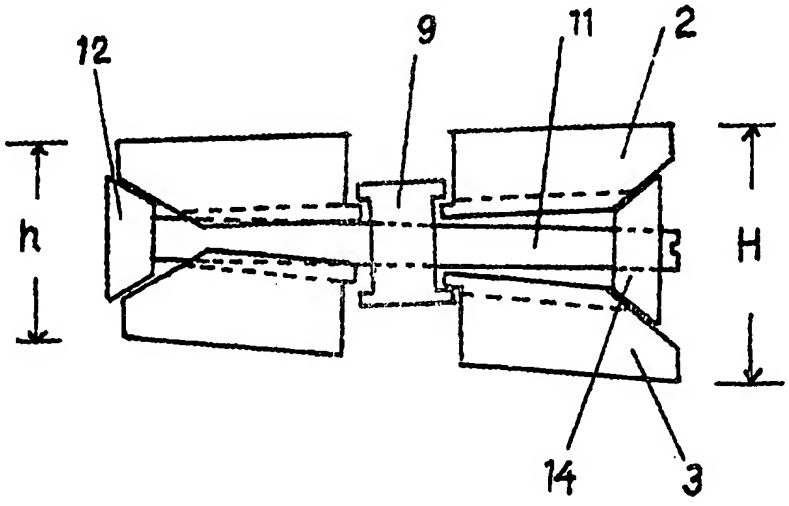
Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

In English translation (filed in Swedish).

(54) Title: AN ADJUSTABLE SPACING DEVICE AND A METHOD OF ADJUSTING THE DISTANCE BETWEEN TWO VERTEBRAE WITH THE AID OF SAID SPACING DEVICE IN SPINAL SURGICAL OPERATIONS



(57) Abstract

The present invention relates to an adjustable spacing device for insertion between vertebrae in spinal surgical operations to adjust the distance between two vertebrae where a fibrocartilage disc is located, wherein the device (1) comprises two mutually superposed elongated plates (2, 3), wherein the plates are provided centrally with a pivot which functions to prevent movement of the plates (2, 3) in the direction of their longitudinal axis but permits the plates (2, 3) to move angularly in relation to one another and at least one of the plates to move perpendicularly to the common plane of the plates (2, 3), wherein the distances at which the plates (2, 3) are spaced apart can be adjusted at each end, individually, with the aid of an adjuster means (7) having two spacing members (12, 14) disposed in a longitudinally extending cavity (6) defined by milled grooves (4, 5) which extend along that side of each plate which faces towards the other plate, and wherein the milled grooves (4, 5) correspond to one another so that together they can receive the adjusting means. The invention also relates to a method for adjusting the distance between two vertebrae with the aid of the spacing device in spinal surgical operations.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	**GB**	United Kingdom	**MW**	Malawi
AT	Austria	**GE**	Georgia	**MX**	Mexico
AU	Australia	**GN**	Guinea	**NE**	Niger
BB	Barbados	**GR**	Greece	**NL**	Netherlands
BE	Belgium	**HU**	Hungary	**NO**	Norway
BF	Burkina Faso	**IE**	Ireland	**NZ**	New Zealand
BG	Bulgaria	**IT**	Italy	**PL**	Poland
BJ	Benin	**JP**	Japan	**PT**	Portugal
BR	Brazil	**KE**	Kenya	**RO**	Romania
BY	Belarus	**KG**	Kyrgystan	**RU**	Russian Federation
CA	Canada	**KP**	Democratic People's Republic of Korea	**SD**	Sudan
CF	Central African Republic			**SE**	Sweden
CG	Congo	**KR**	Republic of Korea	**SG**	Singapore
CH	Switzerland	**KZ**	Kazakhstan	**SI**	Slovenia
CI	Côte d'Ivoire	**LI**	Liechtenstein	**SK**	Slovakia
CM	Cameroon	**LK**	Sri Lanka	**SN**	Senegal
CN	China	**LR**	Liberia	**SZ**	Swaziland
CS	Czechoslovakia	**LT**	Lithuania	**TD**	Chad
CZ	Czech Republic	**LU**	Luxembourg	**TG**	Togo
DE	Germany	**LV**	Latvia	**TJ**	Tajikistan
DK	Denmark	**MC**	Monaco	**TT**	Trinidad and Tobago
EE	Estonia	**MD**	Republic of Moldova	**UA**	Ukraine
ES	Spain	**MG**	Madagascar	**UG**	Uganda
FI	Finland	**ML**	Mali	**US**	United States of America
FR	France	**MN**	Mongolia	**UZ**	Uzbekistan
GA	Gabon	**MR**	Mauritania	**VN**	Viet Nam

AN ADJUSTABLE SPACING DEVICE AND A METHOD OF ADJUSTING THE DISTANCE BETWEEN TWO VERTEBRAE WITH THE AID OF SAID SPACING DEVICE IN SPINAL SURGICAL OPERATIONS

FIELD OF THE INVENTION

The present inventions relates to an adjustable spacing device for insertion between two mutually adjacent vertebrae in spinal surgical operations so as to adjust and increase the distance therebetween, wherein there is formed a space in which a fibrocartilage disc is located and which space has diminished as a result of a pathological change. The invention also relates to a method for adjusting and increasing the distance between two vertebrae by means of the adjustable spacing device.

DESCRIPTION OF THE BACKGROUND ART

Many different solutions for increasing the distance between two vertebrae that has diminished as a result of a pathological change are known to this particular art. An intermediate disc, a fibrocartilage disc, is normally located between adjacent vertebrae. This disc may degenerate as a result of a disease process or pathological change, therewith reducing the distance between the vertebrae. Such conditions are treated with the intention of restoring the distance between the vertebrae and of filling the resultant space with bone transplant so as to achieve bone healing, fusion, between the vertebrae and therewith establish normal vertebrae spacing and stability between the vertebrae.

One method of holding the vertebrae apart during a bone healing process is to replace part of the space with a fixed body of some kind or other, after the vertebrae have been indirectly brought to a normal position. Among other things, cortical bone has earlier been used in this regard. In later times, it has become usual to use "cages", i.e. hollow

implants of different constructions which are filled with cancellous bone, so as to hold the vertebrae apart and also stimulate bone healing between the vertebrae at the same time. All of these solutions involve the insertion of a body which is unable to adapt to the specific shape or configuration that is ideal with respect to the particular individual conditions that prevail from case to case.

SUMMARY OF THE INVENTION

The object of the present invention is to eliminate the aforesaid drawbacks encountered in vertebrae surgical operations of the aforesaid kind and to provide an implant which can be inserted surgically in between the vertebrae and wherein the distance therebetween can be adjusted in place, at both ends, independently of one another, and therewith achieve ideal conditions, i.e. the healthy and natural distances between respective vertebrae at their front and rear parts, which are determined and decided by the different lengths of the ligaments (band structures that surround the vertebrae) and suitably tension the same. In order to be able to maintain normal forward curvature of the spine within the lumbar region, the distance between the rear part of the vertebra interspace shall be longer than the distance within the forward part.

This object is achieved with an adjustable spacing device which comprises two mutually superposed elongated plates, wherein the plates are provided centrally thereof with a pivot which prevents mutual longitudinal movement of the plates but allows the plates to be positioned angularly in relation to one another and permits at least one of the plates to move at right angles to the common plane of said plates, wherein the distance of one plate from the other can be adjusted at each end, individually, by means of an adjuster having spacing means and disposed in a longitudinally extending cavity defined by mutually corresponding

cylindrical grooves milled in respective mutually facing surfaces of said plates, wherein said cavity also includes two circular recesses which extend obliquely from the short ends of the implant and in towards the centre thereof, wherein the deeper ends of the circular recesses either face away from each other and towards the short ends of the implant, and the shallower parts face towards each other in the centre of the implant, or one or both of the deeper ends are disposed in towards the centre on each side of a hole in the implant plates, said hole extending essentially at right angles to the longitudinal axis of the cavity.

The invention also relates to a method for surgically adjusting the distance between two mutually adjacent vertebrae with the aid of an inventive spacing device, wherein one or more spacing devices are inserted into the space between two vertebrae, whereafter the person making the insertion adjusts from one side the distance between the two plates in one spacing device, by first adjusting from one and the same side the position of the most distal end of the implant, by moving a thickened end-part of the adjuster into the cavity and towards the centre or out towards the end-part of the implant, and thereafter adjusting the end of the implant lying most proximal to said person, by moving a second thickened end-part of the adjuster in towards the centre of the implant or out towards said end-part, wherewith both parts are moved away from each other to therewith separate the two vertebra as a result of the varying depth of the cavity. The cavities thus formed by the side of and within the implant are then filled with an appropriate bone transplant material for subsequent bone healing between the vertebrae.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

Fig. 1 is a perspective view of the implant seen obliquely from above.

Fig. 2a is a side view of one of the plates.

Fig. 2b is a sectional view of the plate taken on the line A-A in Figure 2a.

Fig. 3a shows one of the plates from above.

Fig. 3b is a sectional view of the plate in Figure 3a taken on the line B-B in Figure 3a.

Fig. 3c is a sectional view of the plate shown in Figure 3b, taken on the line C-C in Figure 3a.

Fig. 4 is a side view of an adjuster, seen without a centre pin.

Fig. 5 is an end view of the adjuster screw.

Fig. 6 is a side view of the centre pin.

Fig. 7 shows an assembled implant with the adjuster adjusted differently forwards and backwards as seen in a longitudinal sectional view in Figure 1 from one side.

Fig. 8 illustrates another embodiment of the invention and shows the implant when assembled and the adjuster adjusted differently forwards and backwards as seen in a longitudinal view in Figure 1 from one side.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT OF THE INVENTION

The drawings show the main parts of an inventive spacing device. As evident from Figure 1, the spacing device 1 includes two elongated plates 2, 3 each having an obliquely milled groove 4, 5, said grooves together forming a cavity 6 in which an adjuster means 7 is received. An oval hole 8 is provided centrally of each plate and receives a centre pin 9 (see Figures 4-6) which is threaded on the adjuster means 7 and provided with flanges 10 whose diameter is larger than the smaller diameter of the oval hole 8 but smaller than the larger diameter of said hole, to provide a releasable connection for the two plates 2, 3. The plates can be manipulated with the aid of a wrench, key or like tool such that when fitting the implant 1 the upper plate 2 will be

positioned above the lower plate, by first placing the upper plate at an angle of 90° in relation to the longitudinal axis of the lower plate 3 and then rotating said upper plate so that in use said plate will be parallel with the lower plate 3.

The adjuster means 7 is comprised of a threaded rod 11 on which the centre pin 9 is screwed to a position roughly in the centre of the threaded rod 11. The rod 11 has a frusto-conical part 12 formed integrally with one end thereof and is provided with tool-coacting surfaces 13 on its other end. A frustoconical nut 14 is screwed over the tool-coacting surfaces 13 on the rod 11.

Figures 2a-3c illustrate the design of the plates. The plates 2, 3 of the implant 1 are mutually identical. The plates 2, 3 are provided with two oblique, cylindrical recesses 15, 16, e.g. milled recesses, one at each end, and a coaxially extending semi-circular groove 17 which extends in two opposite directions from the oval hole 8 in the centre of the plates 2, 3, out towards the deeper end of the semi-cylindrical recesses 15, 16 through a distance corresponding roughly to half the length of the semi-cylindrical recesses 15, 16 and with a slightly larger than the diameter of the threaded rod 11.

Figure 7 illustrates the mutual relationship of the plates 2, 3 when manipulating the adjuster means 7. The reference h illustrates the height of the implant 1 at one end and the distance between the vertebrae at this end when using the implant in a spinal surgical operation, whereas the reference H indicates the height of the implant 1 at its other end, i.e. the distance between the vertebrae at said other end.

Figure 8 illustrates the mutual relationship of the plates 2, 3 when the adjuster means 7 is manipulated. The reference h indicates the height of the implant 1 at one end thereof,

i.e. the distance between the vertebrae at this end, and the reference H indicates the height of the implant at the other end, i.e. the distance between the vertebrae at said other end. The adjuster means 7 is comprised of a threaded rod 11 onto which the centre rod 9 is screwed to a position roughly in the centre of the rod 11. One end of the rod 11 has formed integrally therewith a frustoconical part 12 whose wider end faces inwards towards the centre of the implant, and the other end of the rod is provided with means for coaction with a wrench, key or like turning tool.

The plates 2, 3 of the implant 1 are mutually identical. The longitudinally extending cavity 6 includes an oblique, cylindrical recess 15, 16 milled in each end of the plates 2, 3, of which recesses 15, 16 the first recess 15 has a deeper part which extends in towards the centre of the plates and a shallower part which extends towards the shorter ends of the plates (2, 3), whereas the other cylindrical recess 16 has a deeper part which extends towards the shorter ends of the plates (2, 3) and a shallower part which extends in towards the centre of the plates. Provided in the centre of the implant is a coaxial semi-circular groove 17 which extends in two mutually opposite directions from the oval hole 8 in the centre of the plates 2, 3 outwardly towards the end parts through a distance corresponding roughly to half the length of the recesses 15, 16 and which has a diameter that is slightly larger than the diameter of the threaded rod 11.

An inventive adjustable spacing device is used in spinal surgery in the following manner:

The adjustable spacing device is preferably used in pairs, one on each side of the space between two mutually adjacent vertebrae. The spacer device is inserted in between the vertebrae and the distance h between the rear parts of the implant plates 2, 3 is adjusted with the aid of a tool

inserted into the tool-coacting part 13 through a centre hole in the frustoconical part 14. The frustoconical part formed integral with the threaded rod 11 is caused to move in the cavity 6 in response to turning of the tool, by virtue of the centre pin 9 being screwed onto the rod 11 and also by virtue of the centre pin 9 being locked in the centre hole 8 of the plates 2, 3 and therewith prevented from moving in the longitudinal direction of the rod. The plates, however, are able to move perpendicularly to the longitudinal axis of the rod, i.e. the longitudinally extending sides can be moved in relation to each other so as to enable lh and LH to be varied, therewith enabling flexible adjustment of the distance between the vertebrae.

The distance between the front parts of respective plates 2, 3 is then adjusted by screwing-in the frustoconical nut 14 on the threaded rod 11 so as to be moved either into or out of the circular cavity 6 in the implant, therewith either increasing or decreasing the distance H between the front ends of the plates. The cavity thus formed by the side of and within the implant is then filled with an appropriate bone transplant for subsequent bone healing between the vertebrae. There is thus obtained in this way a natural, adjustable and flexible spacing between two mutually adjacent vertebrae with the aid of a readily adjusted implant, the ease in which the implant can be adjusted being due to the possibility of adjusting the implant from one direction. Movement of the plates in relation to one another with regard to the distance at which they are spaced apart at both the short ends and the long sides of the plates enables the spinal vertebrae to be brought to a natural position in a surgical operation.

It will be understood that the invention can be modified in many ways within the scope of the following Claims. For instance, the implant plates can be mutually connected in a number of different ways, for instance by means of a spring device or the like disposed around the plates.

CLAIMS

1. An adjustable spacing device for application between vertebrae in spinal surgical operations for the purpose of adjusting the distance between two vertebrae when a fibrocartilage disc located therebetween has diminished as a result of a pathological change, characterized in that the device (1) is comprised of two mutually superposed elongated plates (2, 3), wherein the plates are provided centrally with a pivot means which while preventing movement of the plates (2, 3) in the direction of their longitudinal axes permits the plates (2, 3) to be angled in relation to one another and at least one of the plates (2, 3) to move perpendicularly to the common plane of said plates, wherein the device further includes an adjuster means (7) for adjustment of the distance between the mutually opposing ends of said plates (2, 3), wherein the adjuster means (7) has two spacing members (12, 14) disposed in a longitudinally extending cavity (6) defined by milled grooves (4, 5) that extend along that side of each plate that faces the other plate, and wherein the milled grooves (4, 5) correspond to one another for accommodation of the adjuster means.

2. A device according to Claim 1, characterized in that the longitudinally extending cavity (6) includes an oblique cylindrical recess (15, 16) milled in each end of the plates (2, 3), wherein the recesses (15, 16) have a shallow part which faces towards the centre of the plates and a deeper part which faces towards the shorter ends of said plates (2, 3).

3. A device according to Claim 1, characterized in that the longitudinally extending cavity (6) includes an oblique cylindrical recess (15, 16) milled in each end of the plate (2, 3), wherein one of these two recesses (15, 16), the first recess, has a deeper part which faces in towards the centre of the plates (2, 3) and a shallower part which faces towards

the shorter ends of the plates (2, 3), whereas the other cylindrical recess has a deeper part which faces towards the shorter ends of the plates (2, 3) and a shallower part which faces in towards the centre of the plates.

4. A device according to Claim 1, characterized in that the longitudinally extending cavity (6) includes an oblique cylindrical recess (15, 16) milled in each end of the plates (2, 3), wherein the cylindrical recesses (15, 16) have a shallower part which faces away from the centre of the plates and towards the shorter ends of said plates (2, 3), and a deeper part which faces in towards the centre of the implant.

5. A device according to Claims 1-4, characterized in that the adjuster means (7) is comprised of an elongated screw (11) having formed integrally therewith at one end a conical part (12) which forms one (12) of said spacer members; in that the pivot (9) is comprised of a centre pin (9) screwed onto the screw; and in that the screw (11) has a wrench or key engaging part (13) at the other end and a conical nut (14) which is screwed onto said other end and which forms the second (14) spacing member.

6. A device according to any one of the preceding Claims, characterized by a semi-circular milled groove (17) for receiving and guiding the screw (11), wherein the semi-circular groove (17) extends coaxially with the two cylindrical recesses (15, 16) from the centre of the plates (2, 3) and slightly outwards in the two recesses (15, 16).

7. A device according to Claims 1-4, characterized in that the centre pin (9) has a diameter which fits a central hole (8) provided in each of the plates (2, 3).

8. A device according to Claim 7, characterized in that the central hole (8) in said plates has an oval shape.

9. A device according to Claim 8, characterized in that the centre pin (9) has at each end a flange (10) whose diameter exceeds the small diameter of the oval central hole in the plates (2, 3).

10. A method of adjusting the distance between two mutually adjacent vertebrae with the aid of a spacing device in accordance with Claim 1, characterized by inserting one or more spacing devices into the space between two mutually adjacent vertebrae and thereafter adjusting the distance between the two plates of a spacing device from one side by first adjusting the most distal end of the implant from one and the same side by moving a thickened end-part in the adjuster means in the cavity in towards the centre of the implant or out towards its end-part, and thereafter adjusting the end of the implant most proximal to the person making the adjustment, by moving a second thickened end-part of the adjuster means in towards the centre of the implant or out towards the end-part, therewith moving the plates apart and separating the two vertebrae through a distance which is adjustable and individually adapted to the front and rear ends of the vertebrae and differently for each pair of vertebrae to be treated by virtue of the oblique circular grooves of the cavity in both of said plates, and thereafter filling the cavity formed on one side of and within the implant with an appropriate bone transplant material for subsequent bone healing between the vertebrae and the implant.

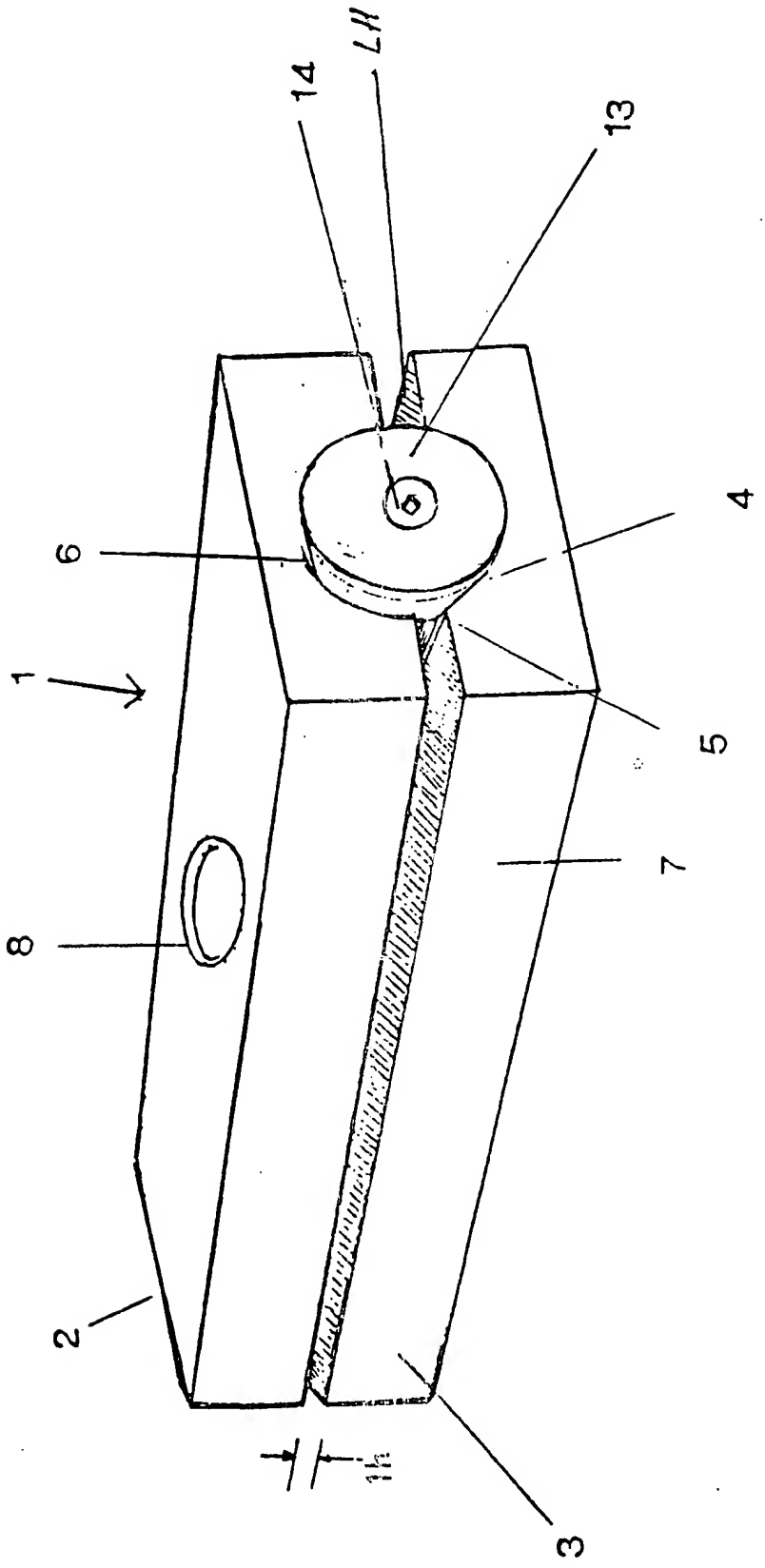


Fig 1

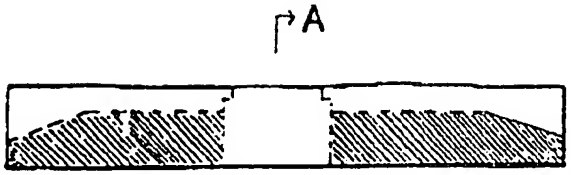
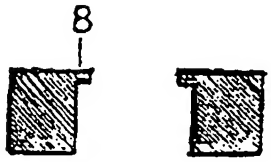
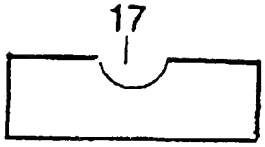


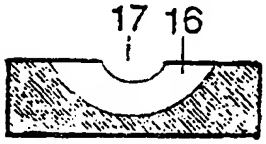
Fig 2a



2b A – A



3b B – B



3c C – C

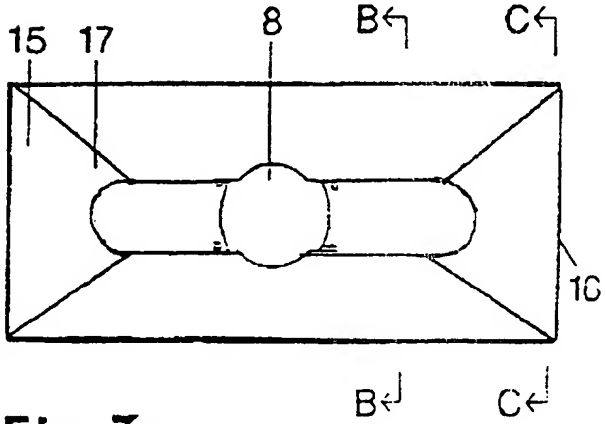


Fig 3a

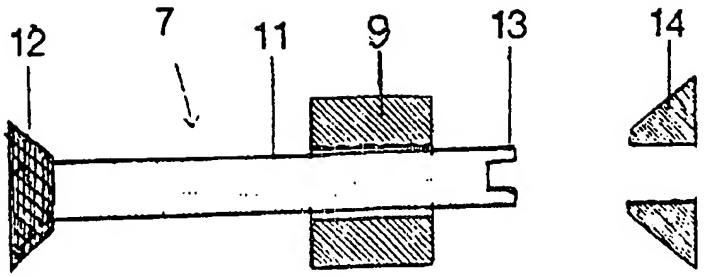


Fig 4

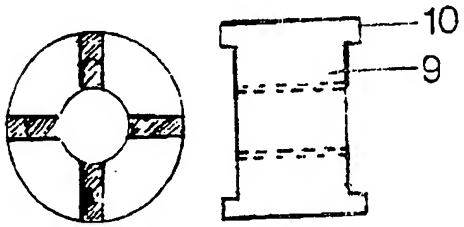


Fig 5 Fig 6

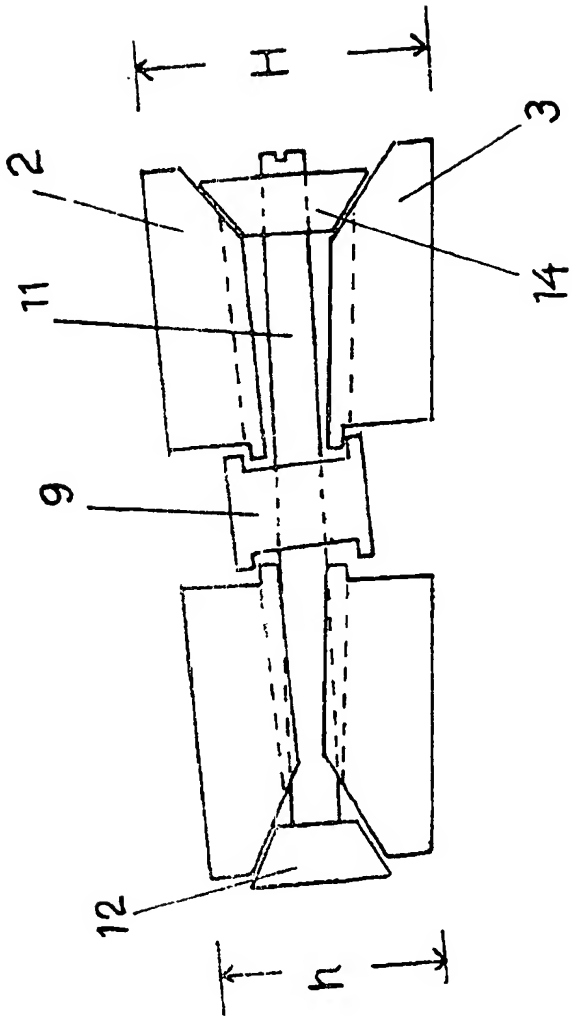


Fig 7

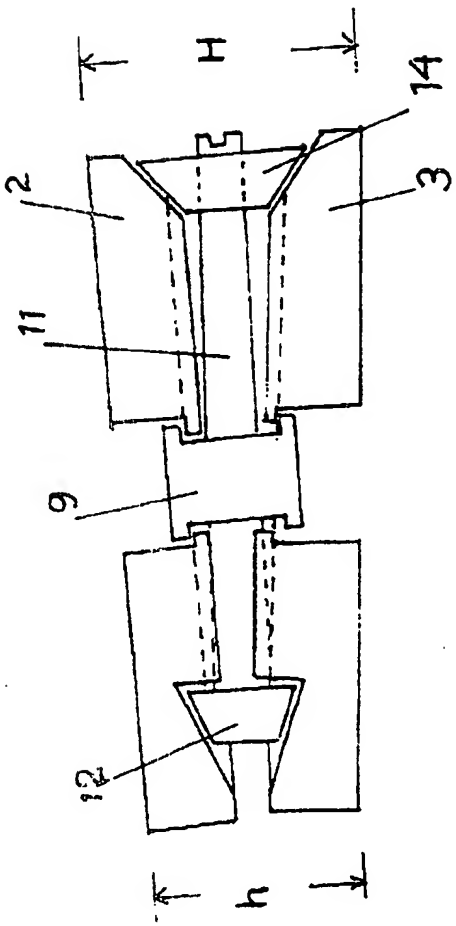


Fig 8